HEALTH DISPARITIES: LINKING BIOLOGICAL AND BEHAVIORAL MECHANISMS WITH SOCIAL AND PHYSICAL ENVIRONMENTS

Release Date: November 4, 1999

RFA: ES-00-004

National Institute of Environmental Health Sciences
National Institute on Aging
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute of Mental Health
National Institute for Occupational Safety and Health
Office of Behavioral and Social Sciences Research

Letter of Intent Receipt Date: January 25, 2000
Application Receipt Date: April 26, 2000

PURPOSE

The purpose of this solicitation is to foster multidisciplinary research that will elucidate underlying mechanisms by which the interaction of social and physical environments leads to health disparities. For purposes of this Request for Applications (RFA), the physical environment includes physical agents (e.g., radiation), chemical agents (e.g., pesticides) and biological agents (e.g, pathogens, harmful algal blooms) to which individuals are exposed in a multitude of settings, including home, school, and workplace. The social environment includes individual and community-level characteristics, e.g., socioeconomic status (SES), education, coping resources and support systems, residential factors, cultural variables, institutional and political forces such as racism and classism, familial factors, and media influences. The ultimate goal of this research is to enhance our understanding of the causes and mechanisms responsible for disparities in health among the U.S. population, especially between lower SES and higher SES groups.

This RFA will support research to strengthen the science base for achieving the goals of the President's Initiative to Eliminate Racial and Ethnic Disparities in Health (see http://raceandhealth.hhs.gov/.) The National Institutes of Health (NIH) has identified as a special emphasis area research related to health disparities. This RFA is one part of a larger NIH and

Department of Health and Human Services (DHHS) effort. Via this particular initiative, the NIH seeks to clarify biological, social, and behavioral processes that lead to health disparities stemming from the interaction of social and physical environments and SES as a basis for ultimately developing intervention strategies. This RFA will not support applications in which the social environment being examined is limited to individual lifestyle choices or to access to and quality of health care (see Background). Such variables are appropriate to this RFA only when coupled to a broader context or array of social environmental factors. Applications submitted in response to this RFA require collaborative efforts between social/behavioral scientists and biomedical scientists and will not be limited by disease end points. In addition, applications must contain a Community Outreach and Education Program (COEP; see Special Requirements) that incorporates strategies for translating research findings into knowledge that can be used to improve public health.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, "Health Disparities: Linking Biological and Behavioral Mechanisms with Social and Physical Environments," is related to one or more of the priority areas.
Potential applicants may obtain a copy of "Healthy People 2000" at
http://odphp.osophs.dhhs.gov/pubs/hp2000

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.
Applications are required to have collaborations between behavioral/social scientists and biomedical scientists as key personnel to undertake the multidisciplinary objectives of this RFA. The roles of the collaborators must be clearly defined. Applications that do not have these collaborations will be considered non-responsive and returned to applicants without review.

MECHANISM OF SUPPORT
All of the Institutes participating in this RFA will use the National Institutes of Health (NIH) research project grant (R01) award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for

an application submitted in response to this RFA may not exceed 5 years. The earliest anticipated award date is September 29, 2000.

Requested amounts should not exceed $400,000 direct costs per year. Awards will be administered under NIH grants policy as stated in the NIH Grants Policy Statement. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

This RFA is a one-time solicitation. The National Institutes of Health (NIH) and the National Institute for Occupational Safety and Health (NIOSH) intend to commit approximately $5,000,000 in FY 2000 to fund new grants in response to this RFA. It is anticipated that up to 10 awards will be made. An applicant may request a project period of up to 5 years and a budget for direct costs of up to $400,000 per year, excluding facilities and administrative (F&A) costs on consortium arrangements. Because the nature and scope of the research proposed may vary, it is anticipated that the size of each award will also vary. Awards pursuant to this RFA are contingent upon the availability of funds for this purpose. Only applications that are found to be of the highest scientific and technical merit will be considered for funding and not all of the funding will be spent if there are not enough highly meritorious applications. Funding in future years will be subject to the availability of funds.

RESEARCH OBJECTIVES

Background

The disparity in health between socioeconomically disadvantaged individuals and those more advantaged has existed for centuries and continues to this day. These health disparities (HD) may be defined as differences in disease incidence, mental illness, morbidity and mortality that exist between specific populations. Disparities are most apparent and closely associated among populations with varying levels of socioeconomic status (SES.) Significant evidence has demonstrated that a gradient exists between SES and health status, with individuals of high SES having better overall health that those of low SES. The most striking health discrepancies result in shorter life expectancy, as well as higher rates of most cancers, some birth defects, infant mortality, asthma, diabetes, behavioral and affective disorders, and cardiovascular disease.

Exposure to toxic environmental and occupational agents can have different effects in different persons of differing age, SES, ethnic background, gender and genetic composition. Some subsets of the population are inherently more susceptible to cellular and genetic damage for a number of reasons, including genetic susceptibility, nutritional status, other social or cultural influences, or in the case of children, the vulnerability of developing systems to environmental insult.

In addition, occupational exposures are known to be distributed differentially, and workers with specific biologic and/or SES characteristics are more likely to have increased risk of work related diseases and injuries. Although the nature and magnitude of risks experienced by people of color have not been thoroughly studied, data on occupational injury deaths indicate that blacks have the highest rates per 100,000 workers compared with those of whites and workers of other races. High-risk populations have been underserved by the occupational safety and health research community, with the result that important unanswered questions remain about the profile of hazards they face, the incidence of work-related injuries and illnesses, the mechanisms of these injuries and illnesses, and the optimal approaches to prevention. Any or all of these factors may contribute to the health disparities observed in socioeconomically disadvantaged and underserved populations.

The relationships among social and physical environments, health, morbidity, and mortality have been long and extensively documented. While the overall relationship of SES to mortality may attenuate in older ages, socioeconomic position continues to be linked to the prevalence of disability and chronic and degenerative diseases, including cardiovascular disease, many cancers, and neurodegenerative diseases. Low SES may result in poor physical and/or mental health by operating through various psychosocial mechanisms such as discrimination, social exclusion, prolonged and/or heightened stress, loss of sense of control, and low self-esteem. In turn, these psychosocial mechanisms may lead to physiological changes such as raised cortisol, altered blood-pressure response, and decreased immunity that place individuals at risk for adverse health and functioning outcomes. Not only may SES affect health, but physical and mental health may have an impact upon the various measures of SES (e.g., education, income/wealth, and occupation) over the life course.

While access to health care may be an important variable that interacts with SES to influence health disparities, this will not be a primary focus of this RFA. Studies indicate that in industrialized nations having equal access to quality health care, an SES gradient still exists in all cause morbidity and mortality. Countries that have universal health care systems, e.g., the

United Kingdom and Scandinavia, still demonstrate SES related health disparities. In fact, a landmark study conducted with British civil servants as subjects ostensibly demonstrated a health outcome gradient in four income groups. Although all workers had access to the same high quality health care, each group had progressively more positive health outcomes with increasing income level and job status. What is noteworthy about this gradient is that it exists across middle and upper income brackets of the British civil servant occupation force. These groups, although more affluent than lower SES groups, did not have health outcomes as good as the group in the highest SES category.

Equally important is the notion that individual behavior and lifestyle choices contribute to disparate health outcomes in lower SES strata. There have been recent data that indicate when individual behavior and lifestyle choices, such as smoking, alcohol consumption, diet and exercise, are corrected for, disparate health outcomes are still observed in lower SES groups. Such findings suggest that access to health care and individual behavior and lifestyle choices are not the major determinants of SES-related disparate health outcomes. Indeed, these results shift research emphasis toward examination of mechanisms by which social and physical environments may interact with SES to produce health disparities. For these reasons, applications which limit the social environment being examined to individual lifestyle choices or to access to and quality of health care will be considered nonresponsive to this RFA and returned to the applicant without review. Such variables are appropriate to this RFA only when coupled to a broader context or array of social environmental factors. Investigators interested in more extensive explorations of the role of individual lifestyle choices or health care as related to health disparities are referred to more relevant initiatives, e.g., Socioeconomic Status and Health Across the Life course (http://grants.nih.gov/grants/guide/pa-files/PA-98-098.html) and Understanding and Eliminating Minority Health Disparities (http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-00-003.html).

INSTITUTE INTERESTS

The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and how they interrelate. The NIEHS achieves its mission through multidisciplinary biomedical research programs, prevention and intervention efforts, and communication strategies that encompass training, education, technology transfer, and community outreach. Programmatically, the NIEHS has a distinguished track record at the forefront of developing innovative community-based research and educational programs that impact low SES and medically underserved communities. The NIEHS Environmental Justice:

Partnerships for Communications Program establishes methods for linking members of a community, who are directly affected by adverse environmental conditions, with researchers and health care providers to ensure that the community actively participates with researchers and health care providers in developing responses and setting priorities for intervention strategies (http://www.niehs.nih.gov/dert/programs/envjust.htm). The Community-based Prevention and Intervention Research Program (CBPIR) utilizes the same type of partnership to implement culturally relevant prevention/intervention activities in economically disadvantaged and/or underserved populations adversely impacted by an environmental contaminant (http://www.niehs.nih.gov/dert/programs/cbpir.htm). The NIEHS also supports Developmental Centers at academic institutions which focus on environmentally related health problems of underserved or underrepresented populations (http://www.niehs.nih.gov/centers/overview/type/devl.htm).
Thus, the NIEHS is actively engaged in support of research that is relevant to health disparities.

The National Institute on Aging (NIA) supports research that may encompass all stages of the life cycle when the overall emphasis and intent of the research is concerned with adult development and aging. Research has shown that lifestyle, economic, social, and environmental influences can have profound effects on health and well-being in adulthood and old age. As part of this RFA, the NIA will support meritorious applications that address SES and health disparities of older Americans with particular attention to: 1)incorporation of lifetime exposures to the physical environment as they interact with SES in affecting subsequent health trajectories, including studies that incorporate residential and occupational histories to facilitate tracking of lifetime environmental exposures; and 2)the interaction of SES with residential choices of the elderly, and associated neighborhood environmental exposures (e.g., violence, crime, transportation options, other amenities), including analyses of small geographic area variations that account for historical change (in terms of both their social and physical aspects). See also Racial and Ethnic Differences in the Health of Older Americans, 1997, National Academy Press (http://www.nap.edu).

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) leads the Federal effort on research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress to improve public health. Rheumatic conditions, e.g., arthritis, systemic lupus erythmatosus (SLE), are among the most prevalent chronic conditions in the United States, affecting more than 40 million persons. But not all population groups are equally impacted. Epidemiological studies have documented marked differences in the prevalence, morbidity and disability associated with specific rheumatic diseases

in Native American, Hispanic, African American and Caucasian populations. Socioeconomic, demographic, cultural, immunogenetic, environmental and clinical variables may all play a role in the presentation and progression of disease. But the relative importance of intrinsic and extrinsic factors differs for the onset compared to progression and disease outcome in these populations. Hispanic and African American SLE patients have more severe disease at the time of presentation than Caucasian patients. In general, disease activity in the early stages of the disease is more severe among minority female patients than among Caucasians. Recent studies suggest that genetic and ethnic factors appear to be more important than socioeconomic determinants in influencing disease activity at the time of disease onset. However, socio-behavioral factors play an increasingly important role in ethnic disparities after onset and may lead to a poorer prognosis in minority populations. The latter is important because it is possibly amenable to more aggressive intervention.

The National Institute of Child Health and Human Development (NICHD) seeks to assure that every individual is born healthy, is born wanted, and has the opportunity to fulfill his or her potential for a healthy and productive life unhampered by disease or disability. In pursuit of this mission, the NICHD conducts and supports laboratory, clinical, sociological/behavioral and epidemiological research on the reproductive, neurobiologic, developmental, and social/behavioral processes that determine and maintain the health of children, adults, families, and populations. Integral to the overall mission of the NICHD is the Institute's mandate to take a developmental approach to consider these processes as they lead from one developmental stage to another -- starting before, into, and through conception, pregnancy, birth, infancy, childhood, adolescence and adulthood through the reproductive years. Thus, an essential part of this research is to understand the origins and accumulation of influences on individuals that would modify their developmental trajectories over the life course and that would lead to health disparities through these stages of development and into older ages. The NICHD will support applications that have an emphasis on population movement and distribution, family behavior and/or socioeconomic neighborhood characteristics as major influences regulating physical environments that produce health disparities.

The National Institute of Mental Health (NIMH) supports research that seeks to eliminate the effects of disparities that impinge on the mental health status of all Americans, including women, children, elderly people, and ethnic/cultural minority groups. NIMH research investments in basic brain and behavioral science have contributed to efforts to reduce the incidence and burden of mental illness. However, there remains a need for scientific research that can tease apart the influences, interactions, and processes of biological, genetic and socioenvironmental factors on the patterns of incidence of mental disorders that reflect disparities. Examination of risk and

protective factors, both behavioral and biological, that mediate or moderate mental health disparities is of great importance and interest.
Moreover, an abundance of epidemiological data has established that mental disorders and medical conditions are frequently co-morbid. The suffering experienced by individuals as a result, and the cost to the nation in lost productivity and health expenditures, is magnified well beyond the suffering and costs associated with individual categories of disorder alone. While the data in some areas of co-morbidity are stronger than in others, relatively little is known about role and processes of environmental risk factors.

The National Institute for Occupational Safety and Health (NIOSH) supports research to identify and investigate the relationships between hazardous working conditions and associated occupational diseases and injuries; to develop more sensitive means of evaluating hazards at work sites, as well as methods for measuring early markers of adverse health effects and injuries; to develop new protective equipment, engineering control technology, and work practices to reduce the risks of occupational hazards; and to evaluate the technical feasibility or application of a new or improved occupational safety and health procedure, method, technique, or system. In 1996, the NIOSH and its partners in the public and private sectors developed the National Occupational Research Agenda (NORA) to provide a framework to guide occupational safety and health research into the next decade -not only for NIOSH, but also for the entire occupational safety and health community. The Agenda identifies 21 research priorities and reflects consideration of both current and emerging needs. One of these priority areas is Special Populations at Risk which was chosen because certain populations of workers are more likely to experience increased risks of diseases and injuries in the workplace as a result of biologic, social, and/or economic characteristics such as age, race, genetic susceptibility, disability, language, literacy, culture, and low income. Specific directed efforts are therefore needed to prevent work-related diseases and injuries in these special populations.

The mission of the Office of Behavioral and Social Sciences Research (OBSSR) is to stimulate behavioral and social sciences research throughout NIH and to integrate these areas of research more fully into other disciplines of the NIH health research enterprise, thereby improving our understanding, treatment, and prevention of disease.

RECENT PROGRESS

Over the past year the NIEHS and other NIH Institutes have undertaken a number of activities to address the task of eliminating health disparities that are influenced by SES. These activities include:

o three regional two and one-half day workshops in Oakland, CA, 1/99, Baltimore, MD, 5/99 and Chicago, IL, 7/99, with the goal of developing a research agenda;
o co-sponsorship of the New York Academy of Sciences Conference in Bethesda, MD entitled: Socioeconomic Status and Health in Industrialized Nations: Social, Psychological and Biological Pathways, 5/99;
o a Concept Forum on SES and HD on the NIH campus in Bethesda;
o the multi-agency sponsored Program Announcement entitled Socioeconomic Status and Health Across the Life course, 8/98.
http://grants.nih.gov/grants/guide/pa-files/PA-98-098.html
o the multi-agency sponsored Program Announcement entitled Low Birthweight in Minority Populations, 1/99.
http://grants.nih.gov/grants/guide/pa-files/PA-99-045.html.

Recommendations from these Health Disparities workshops provided the basis for this RFA. Examples include:

Evaluation of the interconnection between the social environment, physical exposures and psychosocial stress;

Analysis of multigenerational effects of social and physical exposures to investigate links between exposures and health responses;

Examination of the interaction between physical and psychological health, both in terms of well-being and susceptibility;

Assessment of the roles of the social environment (particularly SES), physical environmental and occupational exposures, diet and obesity in disease;

Integration of research, education and service into studies of the biological and social determinants of health disparities;

Integration of qualitative and quantitative research methodologies into studies of social and physical determinants of health disparities; examination of the multiple pathways by which the interaction of social (including SES) and physical environments influence health.

Workshop summaries can be found at: http://www.niehs.nih.gov/dert/gap.htm.

Objectives and Scope

This RFA will support research activities that elucidate the underlying mechanisms by which the interaction of SES and physical and social exposures lead to disparate health outcomes. Applications considering the contributions of physical or social environments in isolation, rather than the interaction of physical and social exposures on health will be considered nonresponsive and returned to the applicant without further review. While the generation of new working definitions of SES, that consider multidimensional interactions of education, income and occupational prestige is an important concept, it is not a focus of this RFA, but is addressed in the multi-agency sponsored Program Announcement entitled Socioeconomic Status and Health Across the Life course (http://grants.nih.gov/grants/guide/pa-files/PA-98-098.html).

The following areas illustrate suitable topics for research.

o Examination of the role of SES, environmental and/or occupational exposures as determinants of health disparities over the life course. What is the role/interaction of social and physical environments at early stages of development, e.g., gestation, childhood, or adolescence, that influence health at later ages and of subsequent generations?

o Analysis of the interaction between race/ethnicity, social and physical environments and SES. An example of race/ethnicity, SES and physical exposures may include political forces (e.g., segregation), compromising physical exposures (e.g., lead or allergens) and neighborhood characteristics,e.g., housing conditions. Opportunities to study mechanisms and genetic susceptibilities that contribute to disparate exposure related outcomes present themselves over multiple developmental stages.

o Assessment of the consequence of interactions between social constructs (e.g., family, peers, neighborhoods and workplace environments) and physical environments on health outcomes related to SES. Socioeconomic status has been most often characterized by the complex interplay between income, education and occupation. More recently, the concept of social capital has been adopted as an additional measure of SES. Social capital encompasses involvement in many types of societal institutions that act to positively impact the function of communities. Included as social capital units, but not limited to, are: church memberships; civic organization memberships; neighborhood organizations; individual stature within the community and the listed social constructs/organizations. Units of social capital for communities could include the overall affluence of the community, the quality and condition of schools, neighborhood housing, quality of recreational facilities, etc. There is a paucity of data concerning the impacts of the lack of social

capital and physical environments on both individuals and communities and their interaction with SES to influence health disparities.
Studies addressing these interactions may be considered.

o Evaluation of the impact of workplace environments on workers within SES strata. Research is needed to determine the mechanisms by which SES and conditions of work interact to determine the severity of emergent disease and injury among these workers and within their communities. Does the excess occupational disease burden among low SES workers result from excess exposures, differential susceptibility, and/or other factors including social factors such as discrimination, language barriers, education or other cultural characteristics?

o Assessment of how SES, social and physical environments in individuals, homes, the community and at the workplace interact with psychosocial stressors to affect allostatic load and thus impact health. Allostasis, the body's ability to adapt and adjust to environmental demands, has been postulated as the mechanistic link between stress and health outcome. Therefore, the allostatic load represents the total burden of physical and social exposures on an individual. Psychosocial stressors include, but are not limited to, discrimination, lack of social capital, depression, low self-esteem, hostility, job instability, unemployment, powerlessness, social isolation, stress, and insecurity. How do physical and social exposures interact with psychosocial stressors and SES to generate adverse health outcomes and functioning in low SES individuals? Studies that explore and define mechanisms on how these factors contribute to health disparities are encouraged.

o Elucidation of multiple pathways by which SES influences social and physical environments and consequently health. There are limited data on SES-related biological mediators of interactions between psychosocial stressors and environmental exposures and their associated health outcomes, e.g., altered hypothalamic-pituitary-adrenal axis function, altered sympathetic and parasympathetic nervous system function, altered molecular and cellular biology of organs, and altered immune responses. The development of biomarkers to link SES and social and physical environments is encouraged, e.g., markers of folate metabolism; uracil-DNA; heat shock proteins, etc. Study of the intersection of these pathways may provide new insights on mechanisms underlying the relationship between SES and exposure-influenced health disparities.

o Examination of multigenerational effects of the social environment and physical exposures to investigate links between exposures and health responses. What is the interaction between physical and psychological health, both in terms of well-being and susceptibility?

o Study of social and physical environmental risk and protective factors and processes that increase or decrease the likelihood of mental disorders, singly or co-morbid with physical disorders, as well as studies of processes that increase resilience to these disorders, including epidemiological studies.

o To the extent that community organizations representing and serving the disadvantaged are partners in research to address health disparities, investigators may develop approaches to integrate research, education and service into studies of the biological and social determinants of health disparities.

o Research on the development of strategies to reduce/eliminate health disparities influenced by the interaction of the social and physical environments. The NIH and the NIOSH recognize that such strategies may extend beyond the traditional confines of biomedical and behavioral research. Studies may be considered that have the capacity to identify and evaluate the role of economic, social cultural, and policy incentives in eliminating or reducing exposure related health disparities.

o Identification of appropriate extant data sets that either contain or link data on population health, social and physical environments. A combination of data sets and/or the use of geocode data to address contextual or multilevel issues may be appropriate. Similarly, researchers may want to use survey data sets matched to death and/or birth records. Micro-level rather than aggregate analyses will be more appropriate for this initiative. Cross national data or data from other countries are appropriate if there is demonstrated relevance to understanding of SES and health in U.S. populations. To address some questions, new data collection and new methodologies may be required. Whenever original data are collected, the National Institutes of Health (NIH) expects grantees to make available research data to the scientific community for subsequent analyses. Data archiving and sharing is appropriate and is encouraged.

SPECIAL REQUIREMENTS

o Annual meetings, to be held in Research Triangle Park, NC, are planned for the exchange of information among investigators. Applicants must budget travel costs for all key personnel to attend these meetings in their applications.

o A Community Outreach and Education Program (COEP) is required for each application. The objective of the COEP is the translation of research results into knowledge used to improve public health. As a part of this effort, each grantee will define the community or population in which the

proposed COEP is to take place and develop productive outreach efforts which are specifically designed to address SES-induced health disparities issues and problems of greatest concern to that community or population. Communities are not necessarily defined by geographic boundaries. In the case of workplace projects, the community may be defined as the work community rather than the community in which the workers live. Workers and management may constitute a workplace community, with impact on both workers' families and on contiguous communities. Appropriate community organizations may include labor unions or other workers organizations. It is particularly important to deal with COEP issues when they arise in a population which may be more susceptible to insults, e.g., children or the elderly. Grantees are encouraged to sponsor local efforts through community organizations and to collaborate with other existing outreach programs in their area, e.g., those supported by other NIH Institutes, other federal agencies (NIOSH, CDC, ATSDR), state or local agencies or health departments. Appropriate activities may include:

1. Continuing professional education that addresses SES, health disparities and treatment and/or disease prevention programs;
2. Education (primary, secondary, and/or college);
3. Information dissemination including communication of research findings to a diverse lay audience in culturally appropriate vehicles;
4. Community issue programs, public awareness seminars, or workshops etc.; and/or
5. Data archiving or other efforts to make data and analyses more accessible and understandable by the lay public, including web-sites and other systems that allow others to access, search, and down-load information, replicate tabulations, or create their own tabulations.

COEP should be a logical outgrowth of the research focus of the application and exhibit potential for mutual benefit due to interactions between investigators and community members. Program staff listed below may be consulted for additional information on COEP. For reference purposes applicants may examine similar COEP efforts conducted by NIEHS Environmental Health Science Centers, such as those at the University of Washington (http://www.niehs.nih.gov/centers/coep/uw-coep.htm) or the University of Medicine and Dentistry of New Jersey (http://www.niehs.nih.gov/centers/coep/mdnjcoep.htm).

COEP activities are a required component of each application submitted in response to this RFA. Applications lacking a COEP component will be considered nonresponsive and be returned without further review. Approximately 10% of the budget should be used in support of outreach or dissemination activities.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which was published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No.11, March 18, 1994, available on the web at: http://grants.nih.gov/grants/guide/notice-files/not94-100.html

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA

in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to:

J. Patrick Mastin, Ph.D.
Scientific Review Administrator
Scientific Review Branch
Office of Program Operations
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-24
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-1446
Fax: (919) 541-2503
Email: mastin@niehs.nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, Email: GrantsInfo@nih.gov.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. The RFA label and line 2 of the application should both indicate the RFA number. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

The sample RFA label available at:

http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

J. Patrick Mastin, Ph.D.
Scientific Review Administrator
Scientific Review Branch
Office of Program Operations
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-24
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-1446
Fax: (919) 541-2503
Email: mastin@niehs.nih.gov

Applications must be received by April 26, 2000. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIH program staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIEHS in accordance with the review criteria stated below. As part of the initial merit review, a process will be used by the initial review group in which applications receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate National Advisory Council.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria all applications will also be reviewed with respect to the following:

o Extent of utilization of multilevel studies, methods and contextual analyses that tease apart host susceptibility, social and physical environments and socioeconomic status (e.g., individual and neighborhood).

o Demonstration of effective collaboration between social/behavioral scientists and biomedical scientists to achieve programmatic goals, i.e., enhanced understanding of the behavioral and biological mechanisms responsible for SES-related health disparities.

o Appropriateness of proposed budget and duration in relation to the project's objectives.

o Effectiveness of the project in establishing a Community Outreach and Education Program that translates research results into knowledge that can be used to improve public health.

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

o The initial review group will also examine the provisions for the protection of human subjects and the safety of the research environment.

Schedule

Letter of Intent Receipt Date: January 25, 2000
Application Receipt Date: April 26, 2000
Peer Review Date: June 2000
Council Review: September 2000
Earliest Anticipated Start Date: September 29, 2000

AWARD CRITERIA

Criteria that will be used to make award decisions include:

- scientific merit (as determined by peer review)
- availability of funds
- programmatic priorities.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Frederick L. Tyson, Ph.D.
Scientific Program Administrator
Chemical Exposures and Molecular Biology Branch
Office of Program Development
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, 111 T.W. Alexander Drive, MD EC-21
Research Triangle Park, NC 27709
Telephone: (919) 541-0176
Fax: (919) 316-4606
Email: tyson2@niehs.nih.gov

Rose Maria Li, MBA, Ph.D.
Chief, Demography and Population Epidemiology

Behavioral and Social Research Program
National Institute on Aging
7201 Wisconsin Avenue, Suite 533
Bethesda, MD 20892
Telephone: (301) 496-3138
Fax: 301-402-0051
Email: rl26b@nih.gov

Susana A. Serrate-Sztein, Ph.D.
Director, Rheumatic Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive
MSC6500
Bethesda, MD 20892
Telephone: (301) 594-5032
Fax: (301) 480-4543
Email: ss86e@nih.gov

V. Jeffery Evans Ph.D., J.D.
Demographic and Behavioral Sciences Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B07, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-1176
FAX: (301) 496-0962
E-mail: Jeff_Evans@nih.gov

Cheryl A. Boyce, Ph.D.
Developmental Psychopathology and Prevention Research Branch
Division of Mental Disorders, Behavioral Research and AIDS
National Institute of Mental Health
6001 Executive Boulevard, Room 6200
MSC 9617
Bethesda, MD 20892-9617
Telephone: (301) 443-0848
Fax: (301) 480-4415
Email: cboyce@nih.gov

Roy M. Fleming, Sc.D.
Director, Research Grants Program
National Institute for Occupational Safety and Health
1600 Clifton Road, N.E.
Building 1, Room 3053, MS D-30
Atlanta, GA 30333
Telephone: (404) 639-3343
Fax: (404) 639-4616
Email: rmf2@cdc.gov

Direct inquiries regarding fiscal matters to:

Carolyn B. Winters
Grants Management Specialist
Grants Management Branch
Office of Program Operations
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
Telephone: (919) 541-7823
Fax: (919) 541-2860
Email: winters@niehs.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.3 93.113, 93.114, 93.115 and 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development

services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index
Return to NIH Guide Main Index